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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/576,724	05/23/2000	Vladka Curin-Serbec	201196/50 (80242/US)	3140

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EXAMINER	
WINKLER, ULRIKE	
ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 06/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/576,724	CURIN-SERBEC, VLADKA	
	Examiner	Art Unit	
	Ulrike Winkler	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,10,12-14,20,24-27 and 31-34* is/are pending in the application.

4a) Of the above claim(s) *10,24-27 and 31* is/are withdrawn from consideration.

5)☒ Claim(s) *6 and 14* is/are ~~allowed~~ allowable

6)☒ Claim(s) *1-5, 12, 13, 20, 32-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The Amendment filed March 8, 2004 in response to the Office Action of November 3, 2003 is acknowledged and has been entered. Claims 1-5, 12-14, 20 and 32-34 are pending and are currently being examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 112

The rejection of claims 1-5, 12, 13, 20 and 32-34 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specifically disclosed monoclonal antibody produced by the hybridoma CNCM- I-2476, does not reasonably provide enablement for other antibodies that are able to bind the prion specific protein structure while not binding the normal cellular form of the prion protein **is maintained** for reasons of record.

Applicant's arguments have been fully considered but fail to persuade. Applicants have amended the claims to add process step to the product claims. Applicant's arguments are that the process of the instant invention differs from the process steps of the prior art. Though the process steps may be different, the prior art clearly indicates that obtaining a specific product having a specific specificity is not a trivial matter. The antibodies of the prior art using the process disclosed in the prior art do not provide antibodies that have the specificity of the instantly claimed antibodies even tough the prior art antibodies are capable of recognizing the same sequence. Fishleigh et al. (U.S. Pat. No. 5,773,572) and O'Rourke (U.S. Pat. No. 6,261,790 B1) teach that the production of antibodies that meet the limitation of binding the

disease specific form while not binding the cellular form of the prion protein in a sample is not a trivial undertaking and is not predictable. Fishleigh et al. and O'Rourke immunize animals with peptides that the ordinary artisan would predict to have the essential 3-dimentional structure of SEQ ID NO: 1 or 2, yet the antibodies produced do not meet the requirement of binding the disease specific form while not binding the cellular form. Applicants have only provided a single antibody made by the disclosed method that meets the requirement of binding the disease specific form while not binding the cellular form. Given the difficulty in the art in producing an antibody that may meet this particular binding requirement, it appears that undue experimentation would be required to practice the claimed inventions with a reasonable expectation of success. Therefore, applicant is enabled only for the single disclosed antibody made from the CNCM- I-2476 hybridoma.

Claim Rejections - 35 USC § 102

The rejection of claims 1, 2, 4, 5, 12, 13 and 20 under 35 U.S.C. 102(b) as being anticipated by Prusiner et al. (U.S. Pat. No. 5,846,533) **is maintained** for reasons of record.

Applicant's arguments have been fully considered but failed to persuade. Applicants have amended the claims to add process step to the product claims. Applicants argument is that the cited art does not disclose the same processes. M.P.E.P. Section 2113 states that: "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made

by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted)

Prusiner et al. discloses in claim 1 that the antibody is characterized by binding to the disease form of the prion PrPSc *in situ*, meaning in the natural or original position of place. In the specification column 38, lines 19-21 the reference indicates that the specific monoclonal antibodies, D4, R2, 6D2, D14, R1 and R10, are part of the claimed scope. Therefore, the instant invention rejected as being anticipated by Prusiner et al.

The rejection of claims 1, 2, 3, 10, 13, 20 and 32-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Korth et al. (Nature, 1997) **is maintained** for reasons of record.

Applicant's arguments have been fully considered but fail to persuade. Applicants have amended the claims to add process step to the product claims. Applicants argument is that the cited art does not disclose the same processes. M.P.E.P. Section 2113 states that: "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted)

Korth et al. discloses the 15B3 antibody, which is able to recognize the disease specific form of the prion protein while not recognizing the cellular form (see figure 1). The antibody is

able to bind the epitope set out in SEQ ID NO:2 and the epitope of SEQ ID NO: 1 having at least one or more substitutions. Therefore, the instant invention is anticipated by Korth et al.

The rejection of claims 1, 2, 3, 5, 10, 12, 13, 20 and 32-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Korth et al. (EP 0 861 900 A1) **is maintained** for reasons of record.

Applicant's arguments have been fully considered but fail to persuade. Applicants have amended the claims to add process step to the product claims. Applicants argument is that the cited art does not disclose the same processes. M.P.E.P. Section 2113 states that: "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted)

Korth et al. discloses the 15B3 antibody, which is able to recognize the disease specific form of the prion protein while ot recognizing the cellular form. The antibody is able to bind the epitope set out in SEQ ID NO:2 and the epitope of SEQ ID NO: 1 having at least one or more substitutions. Therefore, the instant invention is anticipated by Korth et al.

Claim Objections

The objection of claims 4 **is withdrawn** in view of Applicant's amendment.

Allowable subject matter

Claims limited to the specific monoclonal antibody derived from the CNCM- I-2476 hybridoma cell line would be allowable.

Conclusion

Claims 6 and 14 would be allowable if rewritten in independent form.

Claims 1-3, 5, 12, 13, 20 and 32 are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers related this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989). The Group 1600 Official Fax number is: (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center representative whose telephone number is (571)-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 571-272-0912. The examiner can normally be reached M-F, 8:30 am - 5 pm. The examiner can also be reached via email [ulrike.winkler@uspto.gov].

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 571-272-0902.

ULRIKE WINKLER, PHD.
PATENT EXAMINER 5/28/04